

AMENDMENT TO THE CLAIMS

Kindly amend the claims, without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents, as follows.

1-27. (Canceled)

28. (Currently amended) A transformed nonpathogenic bacterium of the genus Bifidobacterium which grows under anaerobic conditions and is transformed with a cloning vector, wherein said cloning vector:

(1) has DNA encoding a protein (a) with anti-tumor activity, or a protein (b) that converts a precursor of an antitumor substance (P) into an antitumor substance, and a promoter and terminator ~~functioning in a bacterium of~~ involved in expressing a gene coding for a histone-like DNA binding protein inherently highly expressed in the bacteria belonging to the genus Bifidobacterium;

(2) can replicate in a bacterium belonging to the genus Bifidobacterium,

(3) can transform a bacterium belonging to the genus Bifidobacterium, and

(4) has ~~[[a]]~~ at least one selective marker that can detect specifically a bacterium belonging to the genus Bifidobacterium transformed with the cloning vector selected from the group consisting of ampicillin resistance, tetracycline resistance, neomycin resistance, kanamycin resistance, nutrition requirements, and medium selection.

29. (Canceled)

30. (Previously presented) The bacterium of the genus Bifidobacterium according to claim 28, wherein the cloning vector is an E.coli-Bifidobacterium shuttle vector.

31. (Currently amended) ~~The bacterium of the genus Bifidobacterium according to claim 30, wherein the cloning vector has a promoter and terminator involved in expressing a gene encoding a histone-like DNA binding protein of a bacterium of the genus Bifidobacterium, and wherein a DNA encoding the protein (a) with anti-tumor activity, or the protein (b) that converts a precursor of an antitumor substance (P) is integrated downstream of the promoter.~~

32. (Currently amended) The bacterium of the genus Bifidobacterium according to claim ~~[[31]]~~ 28, wherein the promoter and terminator are ~~derived from Bifidobacterium Longum and are~~ a promoter and terminator involved in expressing a gene encoding a histone-like DNA binding protein of Bifidobacterium longum.

33. (Currently amended) The bacterium of the genus *Bifidobacterium* according to claim [[32]] 28, wherein the promoter and terminator are a DNA located at nucleotides 1 to 192 of SEQ ID No: 1, and a DNA located at nucleotides 472 to 600 of SEQ ID No: 1, respectively.

34. (Previously presented) The bacterium of the genus *Bifidobacterium* according to claim 33, wherein the cloning vector is pBLES100.

35. (Previously presented) The bacterium of the genus *Bifidobacterium* according to claim 28, wherein the bacterium belonging to the genus *Bifidobacterium* is selected from the group consisting of *Bifidobacterium adolescentis*, *Bifidobacterium longum*, *Bifidobacterium bifidum*, *Bifidobacterium pseudolongum*, *Bifidobacterium thermophilum*, *Bifidobacterium breve*, and *Bifidobacterium infantis*.

36. (Previously presented) The bacterium of the genus *Bifidobacterium* according to claim 35, wherein the bacterium belonging to the genus *Bifidobacterium* is *Bifidobacterium longum*.

37. (Previously presented) The bacterium of the genus *Bifidobacterium* according to claim 28, producing a protein (b) that converts a precursor of an antitumor substance (P) into the antitumor substance.

38. (Previously presented) The bacterium of the genus *Bifidobacterium* according to claim 37, wherein the protein (b) that converts a precursor of an antitumor substance (P) into the antitumor substance is a protein selected from the group consisting of cytosine deaminase, nitroreductase, herpes simplex virus type 1 thymidine kinase and  $\beta$ -glucuronidase.

39. (Previously presented) The bacterium of the genus *Bifidobacterium* according to claim 38, wherein the protein (b) that converts a precursor of an antitumor substance (P) into the antitumor substance is cytosine deaminase.

40. (Previously presented) The bacterium of the genus *Bifidobacterium* according to claim 28, wherein the bacterium of the genus *Bifidobacterium* is *Bifidobacterium longum* 105A/pBLES100-S-eCD, represented by the accession number FERM BP-7274.

41. (Previously presented) A pharmaceutical composition for treating a solid tumor, comprising the bacterium of the genus *Bifidobacterium* according to claim 28.

42. (Previously presented) A kit of a pharmaceutical preparation for treating a solid tumor comprising a pharmaceutical composition according to claim 41 and a second pharmaceutical

composition comprising a precursor of an antitumor substance (P) which is converted into an antitumor substance by a protein (b).

43. (Previously presented) The kit of a pharmaceutical composition for treating a solid tumor according to claim 42, wherein the protein (b) that converts a precursor of an antitumor substance (P) into the antitumor substance is cytosine deaminase, and the precursor of an antitumor substance (P) is 5-fluorocytocine.

44. (Previously presented) A method for treating a solid tumor comprising using the pharmaceutical composition according to claim 41.

45. (Previously presented) A method for treating a solid tumor comprising using the kit of a pharmaceutical composition according to claim 42.

46. (Previously presented) A method for treating a solid tumor comprising using the kit of a pharmaceutical composition according to claim 43.